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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,346	01/14/2004	Heinrich Kladders	1/1447	3492

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EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	**PAPER NUMBER**
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,346	KLADDERS ET AL.	
	Examiner	Art Unit	
	Kristen C. Matter	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. (US 5947118) in view of Datta et al. (US 5871010). Hochrainer et al. disclose an inhaler for the administration of a pharmaceutical composition comprising a mouthpiece 12, an air channel opening into the mouthpiece and a chamber 9 with an air inlet channel wherein the inhaler is capable of receiving a capsule with a composition (see Figure 6). Hochrainer et al. doesn't disclose at least part of the inner surface of the mouthpiece and/or of the air channel and/or optionally the chamber contains elevations and/or depressions with a height/depth of from 0.1 to 100 microns. However, Datta et al. teach an inhaler apparatus with a modified surface for enhanced release of dry powders. Datta et al. disclose the surface of the substrate and the mouthpiece as having elevations and depressions with a depth of one micron to about 2.5 microns (column 2, lines 15-44), which meets the claimed range of 0.1 to 100 microns. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Hochrainer et al. with the depressions taught by Datta et al. in order to decrease the area of contact between the selected medicaments so that medicament particles do not stick to the inside surface of the mouthpiece.

As for claim 2, Hochrainer et al. has disclosed a mouthpiece 12 with an inner surface and a chamber 9 but doesn't disclose either the inner surface of the mouthpiece, the air channel and/or the chamber is produced by microtechnology or nanotechnology over at least 20% of its surface. The claimed phrase "produced by microtechnology or nanotechnology over at least 20% of its surface" is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Hochrainer et al. is silent as to the process used to produce the inner surface of the mouthpiece, air channel and/or the chamber, it appears that the product in Hochrainer et al. would be the same or similar as that claimed.

As for claim 3, Datta et al. disclose the elevations and depressions are separated by spacings of 2 microns, which reads inside the range from 0.1 to 200 microns.

As for claim 4, Datta et al. has taught an inhaler with inner surfaces being made with polycarbonate, for example, (column 7, line 65) which is one of the claimed materials.

In regards to claim 5, Hochrainer et al. has disclosed an inner surface but doesn't disclose the inner surfaces as being formed by processes comprising subtractive or additive treatment selected from stamping, etching, laser ablation, galvanic machining, adhesively attaching a structured film, adhesion of a powder, spraying with suspensions, and depositing sublimates. As set forth in MPEP 2113, product by process claims are NOT limited to manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be

substantially the same or similar is found, a 35 USC 103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even though Hochrainer et al. is silent as to the process used to produce the inner surfaces, it appears that the product in Hochrainer et al. would be the same or similar as that claimed.

As for claims 6 and 7, Hochrainer et al. inherently disclose a Bernoulli inhaler. In addition, the applicant has admitted that Bernoulli inhalers are prior art (paragraph 3, lines 4-7). Hochrainer et al. continue to disclose the inhaler comprising a capsule chamber 9, which is connected to the air channel opening in the mouthpiece 10.

In regards to claims 9 and 10, Hochrainer et al. disclose the inhaler as having a cutting device, which is fitted with at least two sharp spikes, the spikes are capable of being inserted through openings into the capsule chamber (column 3, lines 5-9). Hochrainer et al. continue to disclose an inhaler comprising a cup-shaped lower part 6 open at the top, a plate 8 that covers the opening of the lower part 6 and perpendicularly to which is formed the capsule chamber, a button 10 movable counter to a spring on the capsule chamber, comprising two sharp spikes for opening the capsule, an upper part 13 with the mouthpiece 12 and the air channel which connects the mouthpiece 12 to the capsule chamber 9 so as to be able to convey a powder or liquid or aerosol, and a lid, these elements being joined together by a common hinge element such that they can be moved back and forth relative to one another (column 3, lines 15-18).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. and Datta et al. in view of Kladders (US 4889114). Hochrainer et al. has disclosed everything except the capsule chamber as having a diameter 1.1 to 2.5 times the capsule diameter and a

length 1.02 to 2 times the length of the capsule. However, Hochrainer et al. has taught that the capsule chamber needs to have a diameter large enough to hold the capsule (column 1, lines 19-21). Kladders discloses a similar powder inhaler with a capsule chamber 6 with a diameter 1.1 to 2.5 times the capsule diameter and a length 1.03 to 2 times the length of the capsule (column 2, lines 10-19). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Hochrainer et al. and Datta et al. with the capsule chamber diameter and length as taught by Kladders in order for the capsule to fit in the chamber in order to be completely effective within the system.

Response to Arguments

Applicant's arguments filed 7/11/2006 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Hochrainer et al. disclose all claimed features except for elevations and/or depressions on at least part of the inner surface of the mouthpiece and/or air channel and/or the chamber. However, Hochrainer et al. do disclose a desire to easily clean the inhaler (column 2, lines 42-43). Datta et al. disclose an inhaler with at least part of the inner surface of the mouthpiece covered with elevations/depressions for the purpose of preventing medicament from

sticking to the inner surface for enhanced release of the dry powder. One of ordinary skill in the art would appreciate that prevention of medicament particles from sticking to the inner surfaces of the inhaler would not only enhance delivery of the medicament but would also facilitate cleaning of the mouthpiece due to lack of particles stuck on the inner surface. Regardless, whether the elevations/depressions taught by Datta et al. were provided to Hochrainer et al.'s device for the purpose of enhanced medicament delivery or to facilitate cleaning (both being taught as desirable traits) is not within the scope of the claim and Examiner argues that the inner surfaces of the modified device **may be** kept clean without affecting the delivery characteristics of the composition for the reasons stated above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCMatter
Kristen C. Matter
Examiner
Art Unit 3771

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2/2/07